PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - <u>COMBINED LABEL AND PACKAGE LEAFLET</u>

25 kg kraft paper sacks of three ply with an inner layer of LDPE.

1. Name and address of the marketing authorisation holder and of the manufacturing authorisation holder responsible for batch release, if different

<u>Marketing authorisation holder and manufacturer responsible for batch release:</u>

LABORATORIOS KARIZOO, S.A.
Polígono Industrial La Borda
Mas Pujades, 11-12
08140 – CALDES DE MONTBUI (Barcelona)
Spain

2. Name of the veterinary medicinal product

FLORTEK 40 mg/g Premix for medicated feeding stuff for pigs [ES, CY, HU, PT]
K-FLOR 40 mg/g Premix for medicated feeding stuff for pigs [IT]

Florfenicol

3. Statement of the active substance (s) and other ingredients

Each g contains:

Active substance:
Florfenicol 40 mg

Excipients:
Propylene Glycol (E1520) 10 mg

White to off-white, free flowing powder.

4. Pharmaceutical form

Premix for medicated feeding stuff.

5. Package size

25 Kg

6. Indication(s)

For the treatment and metaphylaxis of swine respiratory disease caused by *Pasteurella multocida* susceptible to florfenicol in infected herds. The presence of the disease in the herd must be established before the product is used.

7. Contraindications

Do not administer to boars intended for breeding.
Do not use in cases of hypersensitivity to the active substance or any of the excipients.

8. Adverse reactions

Commonly observed adverse effects are diarrhoea, perianal inflammation and rectal eversion. Increased serum calcium may also be observed. These effects are transient, resolving on cessation of treatment.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this label or you think that the medicine has not worked, please inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}.

9. Target species

Pigs (fattening pigs)

10. Dosage for each species, route(s) and method of administration

In-feed use
Dosage:
10 mg of florfenicol per kg bodyweight (equivalent to 250 mg of veterinary medicinal product) per day administered for 5 consecutive days.

Administration:
For a daily feed intake of 50 g/kg bodyweight, this dosage corresponds to a rate of incorporation of 5 kg of premix per ton of feed.
Thus, the inclusion level may need adjusting as follows to give the correct dose.

$$\frac{\text{250 mg veterinary medicinal product per kg bodyweight and day} \times \text{Average pig bodyweight (kg)}}{\text{Average daily feed intake (kg/animal)}} = \text{mg of veterinary medicinal product per kg of feed}$$

The maximum rate of incorporation is 12.5 kg/ton, higher rates of inclusion may lead to poor palatability and decreased food consumption.
Under no circumstances should the incorporation rate of the premix be below 5 kg/ton of feed.

It is not necessary to carry out a dilution prior to incorporation into the feed.

In all cases the recommended dose of 10 mg of florfenicol per kg of body weight per day, for 5 consecutive days has to be respected.

To ensure a correct dosage bodyweight should be determined as accurately as possible to avoid underdosing. The required doses should be measured by suitably calibrated weighing equipment.

11. Advice on correct administration

A horizontal ribbon mixer should be used to incorporate the veterinary medicinal product into the feeding stuff. It is recommended that the veterinary medicinal product is added to the mixer containing the feeding stuff ingredients and mixed thoroughly to produce a homogeneous medicated feeding stuff. Medicated feed may also then be pelleted. Pelleting conditions include a pre-conditioning step with steam and then the mixture is passed through a pelleter or extruder under normal conditions.

During granulation, it is advisable to maintain a temperature below 85ºC.

12. Withdrawal period(s)

Withdrawal period(s):

Pigs (fattening pigs)
Meat and offal: 14 days

13. Special storage precautions

This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

14. Special warning(s)

Special warnings for each target species:
Animals showing a decreased appetite and/or a poor general condition should be treated by the parenteral route.

Special precautions for use in animals:
Good clinical practice requires that treatment should be based on sensitivity tests of bacteria isolated from diseased animals. If this is not possible, treatment should be based on local (regional, farm level) epidemiological information on the sensitivity of different strains of bacterial species usually involved in the infectious process.
This premix is intended for the manufacturing of solid medicated feed and cannot be used as it is; the incorporation rate of the premix in feed cannot be lower than 5kg/ton.
This premix contains calcium carbonate, which can lead to a decrease in food consumption and to a phosphorus calcium imbalance in feed intake. Care should therefore be taken to consider the calcium content of the final medicated feed.
Treatment should not exceed 5 days.

In a field clinical study, within a week after the administration of the last dose, the incidence of pigs presenting either mild depression and/or mild dyspnoea and/or pyrexia (40°C) was approx. 20 % in the initially severely ill animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Skin sensitisation may occur.
Avoid skin or eyes contact with the veterinary medicinal product.
Do not handle this product in case of known sensitization to florfenicol or propylene glycol.
Handle this product with care to avoid exposure during incorporation of premix into feed and administration of feed to animals, taking all recommended precautions.
Wear either a disposable half-mask respirator conforming to European standard EN 149 or a non-disposable respirator to European Standard EN 140 with a filter to EN 143, chemically resistant gloves, protective coveralls and goggles while incorporating the premix into feed.
Wash hands thoroughly with soap and water after use of the product or medicated feed
In case of skin contact, wash immediately the affected area and remove contaminated clothing. In case of contact with the eyes, wash immediately with plenty of water.
If you develop symptoms following exposure such as skin rash, you should seek medical advice and take the package leaflet or the label with you.
Do not smoke, eat, or drink when handling veterinary medicinal product or medicated feed.

Other precautions:
Florfenicol is toxic for cyanobacteria and groundwater organisms.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Therefore the use is not recommended during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
None known.

Overdose (symptoms, emergency procedures, antidotes):
In the event of overdose, a reduction in food and water consumption, together with a decrease in bodyweight may be observed. There may be an increase in refused feed and an increase in serum calcium.

Incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

15. Special precautions for the disposal of unused product or waste materials, if any

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.
Dangerous for aquatic organisms such as cyanobacteria. Do not contaminate surface waters with the product or with used containers.

16. Date on which the label was last approved

17. Other information

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

18. The words "For animal treatment only" and conditions or restrictions regarding supply and use, if applicable

For animal treatment only. To be supplied only on veterinary prescription.

Consideration should be given to official guidance on the incorporation of medicated premixes in final feeds.

19. The words "Keep out of the sight and reach of children"

Keep out of the sight and reach of children.

20. Expiry date

EXP {month/year}
Once opened use within 3 months
Shelf life after incorporation into meal or pelleted feed: 3 months

21. Marketing authorisation number(s)

22. Manufacturer's batch number

Batch{number}